

Attorney Docket No.: 6513.200-US
Serial No.: 10/679,638
Filed: October 6, 2003
Inventor: Henrik Bengtsson
Via Facsimile No.: 571-273-8300

REMARKS

Having regard to the Office Action dated August 5, 2005, Applicant has the following comments.

Amendments to claims

Original claim 1 defined a fluid delivery device comprising a pair of electrodes adapted to be mounted in conductive contact with the skin of a subject. Having regard to the specification (see e.g. page 4, lines 16-20, and drawings figs. 1-5) it is clear that the present invention is concerned with a skin-mountable device comprising electrodes which are adapted to be applied externally to the body of a user in a non-penetrating way. Accordingly, amended independent claims 1, 8 and 11 now defines that the pair of electrodes is adapted to be "mounted externally to the body of a subject" and in conductive contact with the skin of the subject.

Claim 6 has been amended to be dependent upon claim 1 instead of any of the previous claims.

As suggested by the Examiner claim 7 has been made dependent upon claim 6 instead of claim 5.

In claim 11 the term "and apply a" has been amended to "and applying a" as suggested by the Examiner.

In all claims reference numerals have been deleted.

Attorney Docket No.: 6513.200-US
Serial No.: 10/679,638
Filed: October 6, 2003
Inventor: Henrik Bengtsson
Via Facsimile No.: 571-273-8300

Claim objections

The Examiner has objected to claims 6 and 7 as being in improper form due to multiple dependencies, correspondingly, the claims have been amended as indicated above.

Claim 11 was objected to because of an informality. The claim has been amended as suggested by the Examiner.

Claim rejections – 35 USC 102 – Say et al (US patent 6,175,752)

The examiner has rejected claims 1, 3/1, 4, 5, and 8-13 under 35 USC 102(b) as being anticipated by Say et al, US patent 6,175,752.

Say et al discloses a drug delivery system 250 comprising a on-skin control unit 254 with at least one subcutaneously implantable sensors 252, and a drug administration system 260 (which may be in the form of a external infusion pump), the on-skin control unit comprising a transmitter for transmitting information to a data storage and controller which again may transfer information to the drug administration system (see column 54, lines 35-61). A counter electrode and/or reference electrode may be placed on the skin of a patient with the working electrode or

Attorney Docket No.: 6513.200-US
Serial No.: 10/679,638
Filed: October 6, 2003
Inventor: Henrik Bengtsson
Via Facsimile No.: 571-273-8300

electrodes being implanted into the patient (see column 7, lines 14-29).

Say et al further discloses that an alarm may be provided which produces a mild electrical shock when activated (see column 46, lines 12-15).

Differences between applicant's invention and Say et al

- (1) Amended claim 1 defines "a pair of electrodes adapted to be mounted externally to the body of a subject and in conductive contact with the skin of the subject". In contrast, Say et al discloses a sensor device comprising two skin-penetrating sensor electrodes (e.g. as shown in fig. 25) which may be supplemented by a skin-placeable counter and/or reference electrode. There is no disclosure that two skin-placeable counter and/or reference electrodes should be used.
- (2) As follows from the above, Say et al also fails to disclose that a voltage can be applied between a pair of skin-placeable electrodes to provide muscle stimulation.
- (3) Further, amended claim 1 defines a fluid delivery device comprising a reservoir and expelling means for expelling a fluid out of the reservoir, this in contrast to Say et al disclosing a modular system which may comprise a sensor unit and a drug administration system adapted to communicate with each other but not integrated to form a device comprising the elements

Attorney Docket No.: 6513.200-US
Serial No.: 10/679,638
Filed: October 6, 2003
Inventor: Henrik Bengtsson
Via Facsimile No.: 571-273-8300

defined in claim 1.

In respect of amended independent claims 8 and 11, these claims now also define that the electrodes are adapted to be "mounted externally to the body of a subject and in conductive contact with the skin of the subject", for which reason the arguments presented in items (2) and (3) also apply to claims 8 and 11.

Claim rejections – 35 USC 102 – Schulman (US patent 4,345,603)

The Examiner has indicated Schulman (US patent 4,345,603) as pertinent to applicants invention, however, Schulman discloses an implantable device comprising two warning electrodes 20, 22 which are adapted to be placed within the body and thus not externally as defined in amended claims 1, 8 and 11.

Claim rejections – 35 USC 103

(i) Based on Say et al (US patent 6,175,752)

As indicated above, Say et al discloses a sensor device which may comprise one or more subcutaneously implantable sensors and a counter electrode and/or reference electrode placed on

Attorney Docket No.: 6513.200-US
Serial No.: 10/679,638
Filed: October 6, 2003
Inventor: Henrik Bengtsson
Via Facsimile No.: 571-273-8300

the skin of a patient.

(1) In respect of the number of counter electrodes and/or reference electrodes placed on the skin of a patient, there is no disclosure or teaching in Say et al (or in any of the other cited references) that more than one should be used. Indeed, based on the intended purpose there would be no technical reason to use more than a single counter/reference electrode.

(2) Say et al is also silent as to between which electrodes a voltage difference should be applied to provide an alarm which produces a mild electrical shock when activated, e.g. between two sensing electrodes or between a sensing electrode and the counter/reference electrode. However, as the alarm arrangement is disclosed in respect of the fig. 18B embodiment (see column 46, lines 12-15) it follows that the skilled person is taught to apply an alarm generating current between the two implanted electrodes 42, 42'. There is no disclosure or teaching that an alarm current should be applied between one of the sensor electrodes or a counter/reference electrode – let alone between two skin-mounted counter/reference electrodes.

Further, having regard to the other cited references (Schulman (US patent 4,345,603) and Fischell (US patent 4,619,653), the skilled person is taught to provide a tickling alarm by applying a current between two implanted electrodes, see e.g. Fischell column 8, lines 6-10. There is no indication or teaching in these references that a corresponding alarm stimulus should

Attorney Docket No.: 6513.200-US
Serial No.: 10/679,638
Filed: October 6, 2003
Inventor: Henrik Bengtsson
Via Facsimile No.: 571-273-8300

be provided by using two skin-mounted external electrodes as used in the present invention.

(3) Say et al basically discloses a sensor device which optionally may be used in combination with drug administration device to form a combined system. There is no indication or teaching that alarm electrodes should be provided on the drug administration device or that the sensor and drug administration devices should be combined to a single, unitary device, this in order to form a device as defined in amended claim 1.

In respect of amended independent claims 8 and 11, these claims now also define that the electrodes are adapted to be "mounted externally to the body of a subject and in conductive contact with the skin of the subject", for which reason the arguments presented in items (2) and (3) also apply to claims 8 and 11.

(i) Based on Schulman (US patent 4,345,603) or Fischell (US patent 4,619,653)

As Schulman and Fischell are concerned solely with implantable drug delivery devices, it follows that they cannot provide the skilled person with a teaching or an incentive for providing an external drug delivery device with a pair of external electrodes to provide an alarm.

Attorney Docket No.: 6513.200-US
Serial No.: 10/679,638
Filed: October 6, 2003
Inventor: Henrik Bengtsson
Via Facsimile No.: 571-273-8300

Advantages of the present invention

Apart from the cited prior art failing to disclose or teach the present invention, the present invention provides advantages which are not and cannot be achieved with the devices known from the cited prior art. For example, by using two external non-penetrating electrodes, the skin-mountable device of the invention does not rely on the use of a penetrating member primarily adapted for a different purpose as an electrode, e.g. an insertable sensor or a transcutaneous infusion device such as a cannula or needle. Correspondingly, such a member does not have to be modified to work as a stimulation electrode thus allowing a greater degree of freedom of design. In the same way the two external non-penetrating electrodes can be optimized for a single purpose.

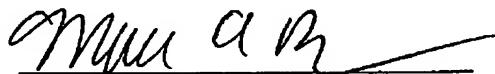
Attorney Docket No.: 6513.200-US
Serial No.: 10/679,638
Filed: October 6, 2003
Inventor: Henrik Bengtsson
Via Facsimile No.: 571-273-8300

Conclusion

In conclusion, Say et al alone or in view of any of the references on file fails to make obvious to the skilled person an alarm device as defined in amended claims 1, 8 and 11. All further claims are dependent upon an independent claim. In view of the above, applicants respectfully submit that all claims are in condition for allowance. The Commissioner is hereby authorized to charge any fees in connection with this application and to credit any overpayments to Deposit Account No. 14-1447. The Examiner is hereby invited to contact the undersigned by telephone if there are any questions concerning this amendment or application.

Respectfully submitted,

Date: November 7, 2005



Marc A. Began, Reg. No. 48,829
Novo Nordisk Inc.
100 College Road West
Princeton, NJ 08540
(609) 987-5800

Use the following customer number for all correspondence regarding this application.

23650

PATENT TRADEMARK OFFICE